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TO AMEMBASSY TEL AVIV

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E.O. 11652: N/A

TAGS: TBIO, OSCI, IS

SUBJECT: PROPOSED RESEARCH CONTRACT: STUDY OF THYROID
TUMOR RISK FROM SCALP X-IRRADIATION DURING CHILDHOOD

1. FOOD AND DRUG ADMINISTRATION IS CONSIDERING SUBJECT
RESEARCH CONTRACT WITH CHAIM SHEBA MEDICAL CENTER, TEL
HOSHOMER, ISRAEL.

2. PURPOSE OF PROJECT IS TO INVESTIGATE FURTHER AN UNEXPECTED
AND IMPORTANT NEW FINDING CONCERNING RADIATION-INDUCED
THYROID TUMORS. IN STUDY OF "DELAYED EFFECTS OF SCALP
X-IRRADIATION" BEING CONDUCTED IN ISRAEL UNDER SFCP
RESEARCH AGREEMENT 06-009-3, THYROID CANCER HAS BEEN
FOUND ASSOCIATED WITH LOWEST THYROID ABSORBED RADIATION DOSE
YET REPORTED (6.5 RAD). ESTIMATED RISKS OF THYROID TUMOR
INDUCTION HAVE BEEN ONLY MINIMAL ESTIMATES BECAUSE
METHODOLOGY OF STUDY DID NOT PERMIT COMPLETE ASCERTAINMENT
OF MALIGNANT TUMORS OR IDENTIFICATION OF BENIGN NEOPLASMS.
PROPOSED STUDY WILL HELP TO OBTAIN AS FULL AN ACCOUNT AS
POSSIBLE OF THYROID ONCOGENESIS IN STUDY POPULATION AND
THUS MAKE POSSIBLE MORE PRECISE RISK ESTIMATES.

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PAGE 02 STATE 148707

3. STUDY POPULATION CONSISTS OF 10,902 IRRADIATED CASES, 10,902 POPULATION CONTROLS AND 5,496 SIBLING CONTROLS. IRRADIATION WAS PERFORMED DURING THE YEARS 1949-1960. MALIGNANT THYROID TUMORS WERE IDENTIFIED THROUGH CENTRAL ISRAELI TUMOR REGISTRY AND THE DEATH CERTIFICATES FILE FOR PERIOD 1960-1972.

4. PROPOSED STUDY WILL INVOLVE:

ASCERTAINMENT OF THYROID TUMOR CASES IN STUDY POPULATION SHALL BE COMPLETED BY SCREENING ALL OPERATING ROOM RECORDS OF ALL HOSPITALS FOR DIAGNOSED CASES OF
- THYROID CANCER DURING THE PERIOD 1950-1959, AND AFTER 1972.

- BENIGN THYROID TUMORS SINCE 1950, A FOLLOWUP PERIOD OF ABOUT 25 YEARS.

ALL TUMOR CASES SHALL BE CHARACTERIZED AS TO IRRADIATION OR CONTROL STATUS, SEX, YEAR OF BIRTH, DATE OF IRRADIATION, AGE OF IRRADIATION, PLACE OF IRRADIATION, NUMBER OF IRRADIATIONS, COUNTRY OF ORIGIN, DATE OF IMMIGRATION, DATE OF DIAGNOSIS, HOSPITAL, HISTOLOGIC DIAGNOSIS, DATE AND CAUSES OF DEATH.

5. FDA WOULD APPRECIATE LEARNING IF POST SEES ANY OBJECTIONS TO THE PROPOSED STUDY AND ADVISE ASAP AS FDA WISHES FUND STUDY THIS FISCAL YEAR. KISSINGER

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